

Our ref: CER-298



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: C. SIKORSKI :

Serial No. : 09/843,181 :

Group : 1623

Filed : April 26, 2001 :

Examiner: E. NMS White

Title : Agglomerated :
Modified Cyclo-
dextrin and Process:
for Making Same

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DECLARATION

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

S i r:

I, Chris Sikorski, hereby declare and say as follows:

1. I am one of the named Inventors in the instant Application.
2. It has been brought to my attention that this Application has been rejected based on US Patent No. 6,153,746 to Shah, US Patent No. 5,980,971 to Walsh, US Patent No. 4,127,944 to Giacobello, and US Patent No. 5,070,081 to Majid.

3. In order to demonstrate the difference between the drum dryer and the spray dryer, tests have been performed and are presented herein. These tests have been performed by me or under my direct supervision and control.
4. Five products were made in accordance with the present Invention and, specifically, Examples 1-5 were prepared for purposes of comparison between a drum drying technique and a spray drying technique. Each of the products was prepared as taught in Examples 1-5 of the Application on pages 11-14. Examples 1-4 were prepared using the drum drying technique of the present Invention, while Example 5 was prepared using a conventional spray drying technique. The Table on page 14 of the Application illustrates the particle size distribution and dissolution rates of drum drying versus spray drying.
5. Example 1 was prepared by gradually introducing a hydroxypropyl beta-cyclodextrin containing 55% total solids onto the applicator rolls of a roll dryer of the type shown in Figure 1 of the Application. The dryer was operated at the following conditions:

1 rpm on the drying roll

100 psig steam on the drying roll

2 valley feed

no cooling water on applicator roll

A scraping blade held at a fixed position above the drying roll as shown in Figure 1 was used during the drying process to continuously recover the dried product.

6. Example 2 was prepared according to Example 1 except that the dryer drums were rotated at 5 rpms.
7. Example 3 was prepared according to Example 1 except that a solution was used having a solids content of 64% by weight.
8. Example 4 was prepared according to Example 1 except that the dryer drums were rotated at 5 rpms and the solution had a solids content of 64% by weight.
9. Example 5 was prepared by conventionally spray drying a solution of hydroxypropyl beta-cyclodextrin containing approximately 25% solids using a standard

spraying tower. The dryer was operated at the following conditions:

inlet temperature between 200 and 220°C

outlet temperature between 95 and 105°C

10. The following Table compares the results of the drum dried product versus the spray dried product.

**PARTICLE SIZE DISTRIBUTION AND DISSOLUTION DATA FOR
EXAMPLES 1-5**

				<u>X10</u>	<u>X50</u>	<u>X90</u>	Dissolution Rate (min) for 10% solids at 24°C
Example 5	Spray Dried	25% solids		3.74	14.12	29.72	15.33
Example 1	Drum Dried	55% solids	1 rpm	7.14	34.88	111.46	2.75
Example 2	Drum Dried	55% solids	5 rpm	6.02	30.22	103.30	1.50
Example 3	Drum Dried	64% solids	1 rpm	9.75	56.54	180.85	3.50
Example 4	Drum Dried	64% solids	5 rpm	7.29	35.62	115.98	5.50

X10: 10% of particles are smaller than...

X50: 50% of particles are smaller than...

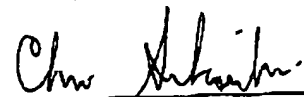
X90: 90% of particles are smaller than...

Results are expressed in microns

11. The product of the present Invention has a substantial number of drum dried particles (50%) that are larger than 30 microns while a substantial number of spray dried particles (90%) were smaller than 30 microns.
12. The drum dried and spray dried product were tested to see how fast they dissolved in water. It was found that the dissolution time of the drum dried product was about three to ten times faster than the spray dried product.
13. In handling the dried product from both the spray drier and the drum drier, it was noted that the spray dried product produced dust while the drum dried product produced no dust.
14. Pictures were taken of each product and are attached to the application as filed. As seen in the Figures, Figures 1-4 illustrate the drum dried product while Figure 5 illustrates the spray dried product. As can be seen, the drum dried product is flake shaped while the spray dried product was bead-like in appearance.

15. I consider the difference between the spray dried product and the drum dried product to be surprising and unexpected because I would not have expected such difference between the two products based on the two different drying techniques for a uncomplexed modified cyclodextrin dried from an aqueous solution of uncomplexed modified cyclodextrin.

It is declared by undersigned that all statements made herein of undersigned's own knowledge are true and that all statements made on information and belief believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under section 18 US Code 1001, and that such willful false statements may jeopardize the validity of this Application or any patent issuing thereon.



Chris Sikorski

Dated: This 10 day of September 2003.